



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 3, 2015

WhiteCap Technologies LLC
% Mr. Young Chi
President
Bio-Med USA Incorporated
27 New England Drive
Ramsey, New Jersey 07446

Re: K150027

Trade/Device Name: CYMA Co2 laser

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser surgical instrument for use in general and plastic
surgery and in dermatology

Regulatory Class: Class II

Product Code: GEX, ONG

Dated: January 8, 2015

Received: January 13, 2015

Dear Mr. Chi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for use statement

510 (K) number : K150027

Device name : CYMA co2 laser

Indication for use : CYMA Co2 laser systems when used in non fractional mode is intended use for Incision, Excision, Ablation, Vaporization and Coagulation of body soft tissues including intraoral tissues, in medical specialties including Dermatology and Plastic surgery, Otorhinolaryngology(ENT), Gynecology, Neurosurgery, Dental and Oral Surgery and Genitourinary Surgery .

When used in Fractional mode intended use for Skin Resurfacing.

Prescription use xx or/and Over the Counter use _____
(Part 21 CFR 801 Sub part D) (Part 21CFR 801 Sub part C)

Please do not write below line-continued an another pages if needed

Concurrence of CDRH, office of Device Evaluation (ODE)

510 (K) Summary

As required by CFR 807.92(c)

1. Sponsor

Prepared Jan 5, 2015

WhiteCap Technologies, LLC.
450 W 910S Suite 300,
Heber City, UT84032
t: 1 435 503 6308 f: 435 654 0731

2. Submitter and Contact person

Bio-Med USA Inc.
Young Chi, President.
27 New England Drive, Ramsey, NJ 07446. U.S.A.
t: 1-973 278 5222 f: 1 201 934 6030
e mail: biomedusa@msn.com

3. Name of Device

Trade name : CYMA
Classification name : Powered, Laser surgical instrument
Common name : Co2 laser
Regulation : 878.4810 Class II
Classification Panel : General and Plastic Surgery.
Product Code : GEX
Subsequent Product Code: ONG

4. Legally marketed Predicate Device

| | | | |
|---------|--------------|-----------|-------------------|
| K123573 | YOULASER Co2 | Co2 laser | Quanta System SPA |
|---------|--------------|-----------|-------------------|

Proposed device are applying same Characteristics such as Design, Construction, Energy, Repetition rate, Cooling Systems, Intended use, Technical specification as predicate device, accordingly there has no new issues raised for safety and effectiveness.

5. Device Description

The CYMA Co2 laser System are emitting a invisible infrared laser with maximum power of 30 watt at 10.63 um and consist of .Infrared light laser oscillation in tubes ; Power supplies, with non contacted mode hand pieces, LCD touch screen display, on this panel also has key switch, emergency red button and the operation led are inserted and consists of main function,

Optic main Bench assemble, Fiber optic Hand pieces, Co2 laser Scanner laser tube : placed in the mixed crystals of copper pipe to the heater and produces a laser beam,

Resonator : amplifies the beam, Cooling system, LCD control Panel, Foot Pedal Switch

Microcontroller manages the voltage and the Co2 laser Source.

This converted light energy creates the Co2 infrared laser and exhaust from the crystal is amplified into a specific wave length. Laser energy produced is delivered to the tissue by means of an articulated arm and a specially designed multi spot Hand Piece.

The Physician can optimize the effect for different applications by controlling the energy of the laser pulse and the spot size of the treatment beam, and is able to activate laser emission using Foot Switch.

6. Performance test

Clinical data is not presented in this submission,
but manufactured in accordance with both mandatory and voluntary below standard

IEC60601-1 part 1 : General requirement for basic safety and essential performance.
IEC60601-1-2: 2007 E M C test
IEC60601-2-22 Part 2, Particular requirements for safety of diagnostic and Therapeutic laser
IEC60825-1 :2nd ED, Equipment classification and requirement.

Proposed device, demonstrates no significant different compare to the predicate device

7. Intended use

CYMA Co2 laser systems when used in non fractional mode is intended use for Incision, Excision, Ablation, Vaporization and Coagulation of body soft tissues including intraoral tissues, in medical specialties including Dermatology and Plastic surgery, Otorhinolaryngology(ENT), Gynecology, Neurosurgery, Dental and Oral Surgery and Genitourinary Surgery .

When used in Fractional mode intended use for Skin Resurfacing.

8. Biocompatibility, Sterilization

This device are non-contacted mode, and do not need sterilization.

9. Conclusion.

CYMA Co2 laser system, in this submission, is substantially equivalent to several already cleared predicate device in respect to the Intended use, Main function, Technology, Principal operation and performance.
And every Safety test report show it as safe and effective as predicate device and it does not raise any additional issues for safety and effectiveness.